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IMPROVED FATIGUE AND PHYSICAL FUNCTION ARE CORRELATED WITH HEALTH-RELATED QUALITY OF LIFE IN PSORIATIC ARTHRITIS SUBJECTS TREATED WITH APREMILAST: RESULTS FROM A PHASE 2, RANDOMIZED, CONTROLLED STUDY

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OBJECTIVES: Psoriatic arthritis (PsA) is an inflammatory arthritis with deleterious effects on health-related quality of life (HRQOL). We evaluated the effect of apremilast (APR) on patient-reported outcomes (PROs) in PsA subjects and the correlation between the 36-Item Short-Form Health Survey (SF-36) domains and disease-specific measures of physical function and fatigue. **METHODS:** A phase II, multicentre, double-blind, placebo-controlled study randomised 204 subjects with active PsA (duration >6 months; ≥3 swollen joints; ≥3 tender joints) 1:1:1 to oral APR 20mg BID (APR20), 40mg QD (APR40), or placebo for 12 weeks. PROs included Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), Health Assessment Questionnaire–Disability Index (HAQ-DI), pain visual analogue scale (VAS), and SF-36 domain scores. Correlations between the HAQ-DI, pain VAS, and FACIT-F and the SF-36 Physical Function (PF), Bodily Pain (BP) and Vitality (VT) domains were described with statistical significance. **RESULTS:** At week 12, mean change in PF, BP, and VT was −2.1, 2.7, and 3.1 with placebo; 6.2 (P=0.012 versus placebo), 11.5 (P=0.001 versus placebo), and 6.6 (P<0.05 versus placebo) with APR20; and 3.8, 7.9 (P=0.037 versus placebo), and 3.7 with APR40, respectively. Mean change in HAQ-DI was −0.1, −0.2, and −0.2 with placebo, APR20, and APR40. Mean change in FACIT-F was 0.5, −4.1 (P<0.025), and −4.3 with placebo, APR20, and APR40. Mean percent change in pain VAS was 7.4%, −14.5%, and −15.1% with placebo, APR20, and APR40. Moderate (>0.30≤0.60) and statistically significant (P<0.001) correlations were evident between pain VAS and BP (−0.55), HAQ-DI and PF (−0.43), and FACIT-F and VT (0.55). High (>0.60), statistically significant (P<0.001) correlations were observed for FACIT-F versus VT (0.66) with APR20 and HAQ-DI versus PF (−0.73) with APR40. **CONCLUSIONS:** Treatment of PsA with APR20 was associated with statistically significant improvements versus placebo in FACIT-F and HRQOL. Moderate to high correlations were evident among PROs.

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NEW DEVELOPMENTS IN THE ANKYLOSING SPONDYLITIS QUALITY OF LIFE (ASQOL) SCALE

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OBJECTIVES: The PsAQoL is a measure of quality of life (QoL) specific to psoriatic arthritis (PsA) first published in 2003. Content of the measure was derived entirely from qualitative interviews conducted with UK PsA patients. New language versions have since been developed for several European countries, the US, Canada, Argentina and Brazil. Interest in the PsAQoL has increased lately due to the need to determine changes in QoL associated with new biological treatments. In recent years there has been a move towards conducting clinical trials in developing countries. This has increased interest in adapting patient-reported outcome measures developed in Europe and the United States for use in new regions of the World. An important question remains to be answered; can such measures provide valid assessment of QoL in these regions? **METHODS:** New adaptations are currently being produced for Eastern Europe (4), the Middle East (2), Central and South America (2) and Asia (5). The measures are being translated (using the two panel methodology required for needs-based measures) and tested with local patients by means of cognitive debriefing interviews. **RESULTS:** To date cognitive debriefing interviews have confirmed the adapted measures' acceptability to patients who found it easy to understand and complete. The adaptations also have good internal consistency (alphas > 0.85) and reproducibility (test-retest reliability coefficients: > 0.85). The adaptations also exhibited construct validity by their ability to distinguish groups of PsA patients that varied by perceived disease severity and general health and by correlating as expected (moderately) with the Nottingham Health Profile. **CONCLUSIONS:** It is intended to use Item Response Theory analyses to determine whether respondents in the developing countries answer the PsAQoL in the same way as those in Western countries. This will show whether the scales work validly in the developing countries.

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SENSITIVITY OF PRO'S TO DETECT CHANGES IN QUALITY OF LIFE IN PATIENTS TREATED WITH A BIOLOGIC AGENT

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OBJECTIVES: To investigate whether patient reported outcomes in patients who had been prescribed etanercept, an anti –TNF inhibitor, by their specialist could detect changes in quality of life over time. A longitudinal evaluation was designed to collect naturalistic data about their condition, medications and health care experience. **METHODS:** The evaluation was conducted throughout the UK using a web-based system supplemented by telephone reporting PROBE (patient reported outcomes based evaluation). Outcome measures included demographic data, the condition, previous treatment, current medications, patients' experiences of their condition, treatment and healthcare and quality of life. **RESULTS:** A total of 344 people participated in the evaluation at baseline, 290 online and 54 by telephone with a mean age of 53 years and 62% female. 191 of these patients had Rheumatoid Arthritis, 44 Psoriatic Arthritis, 43 Ankylosing Spondylitis, 35 psoriasis and 31 other/missing data. Patients were severely affected by their condition as noted on their quality of life measures at baseline. Treatment had a marked beneficial effect for patients as recorded by all measurement tools. All scores given in order. Baseline month 6 mean (SD) clinical global impression 1 worst health 7 best health 3.15 (1.09) to 4.31 (1.50) p<0.001. EQ 5D Questionnaire 0.0 worst health 1.0 best health 0.39 (0.34) to 0.64 (0.27) p<0.001. DLQI 30 worst effect 0 no effect on life 14.57 (6.74) to 3.69 (6.14) p<0.001. HAQ. 0 no difficulty 3 unable to perform action 1.77 (0.63) to 1.25 (0.73) p<0.001. **CONCLUSIONS:** This evaluation shows that patients have significant impairment of their quality of life before commencing a biologic agent across a range of conditions. Treatment with the biologic agent showed a sustained improvement in their quality of life up to 6 months. The PROBE methodology (web-based system supplemented by telephone reporting) successfully captured changes in patient reported quality of life measures.

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QUALITY OF LIFE FOR THAI HIP FRACTURE PATIENTS: ASSESSMENTS WITH MEDICAL OUTCOMES STUDY, A 36-ITEM SHORT FORM SURVEY (MOS SF-36) AND ONE-YEAR HEALTH CARE RESOURCE UTILIZATION IN A PUBLIC HOSPITAL

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OBJECTIVES: Hip fracture is a major health burden in Thailand. We determined the health-related quality of life for patients living with hip fracture, correlated factors and relationships with one-year health care resource utilization. **METHODS:** A self-administered Medical Outcomes Study 36-item Short Form Survey (MOS SF-36) questionnaire was mailed to patient after hospital discharge over 6 months. A cross-sectional analysis of MOS SF-36 was carried out among 119 hip fracture patients of Chiangrai Hospital. Healthcare resource utilization was follow-up for one year taken from hospital database. **RESULTS:** Response rate was 67 % and a mortality rate after one year was 14%. The Cronbach's alpha coefficients of eight items symptoms domain, and of two items of summary score components for physical function and mental function of MOS SF-36 Thai questionnaire were 0.769 and 0.831 respectively. The mean ±SD (95 % CI) for summary score components for physical and mental functions were 40.1±11.6 (38.0-42.2) and 48.0±10.2 (46.1-49.9) respectively. There was no significant difference of mean ±SD scores for global health between gender (p=0.103), age (65≤ and >65years) (p=0.798), BMI (20.0≤ and >20.0kg/m2) (p=0.693), hip fracture management types (surgical and nonsurgical) (p=0.386) and types of hip fracture (p=0.188) respectively. Presence of co-morbidity was a highly correlated factor for summary score components for physical (p=0.030), and mental (p<0.001) functions. There was no significant correlation between overall one year healthcare resource utilization with both summary score components for physical (p=0.567) and mental (p= 0.357) functions. **CONCLUSIONS:** Health-related quality of life assessments with MOS SF-36 for Thai hip fracture patients are reliable. Thai hip fracture patients reflect poorer physical functions than mental functions. Presence of co-morbid disease is a factor well correlated with poorer health-related quality of life. There is no significant correlation between one-year health care resource utilization and health-related quality of life for Thai hip fracture patients.

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CONCEPTUAL MODEL OF THE IMPACT OF HIP FRACTURE ON PATIENTS' LIVES

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OBJECTIVES: Hip fractures are traumatic and debilitating events which are more common in the elderly, and associated with loss of mobility and independence, mortality, and significantly increased health care resources. Our objectives were to evaluate the impact of hip fractures on patients' lives and summarise the patient experience in a conceptual model. **METHODS:** Twenty-one adults aged ≥50 years who experienced a hip fracture in the previous 2-18 months were recruited to participate in in-depth semi-structured interviews exploring their experience of hip fracture and impacts on their life. Thematic qualitative analysis of interview transcripts was conducted using ATLAS.ti software to identify areas of impact (concepts) and explore the interrelationships between concepts. A conceptual model was developed based on this analysis. **RESULTS:** Participants were mostly female (n=12) with mean age 75 years (range 53-87 yrs), and 5 participants had a hip fracture treated with partial or total hip replacement. Pain and limited mobility were commonly reported by participants and were associated with increased physical inactivity. Mobility limitations included: difficulties walking (distance, speed, up/down stairs), restricted or difficult lower limb movements, getting or standing up and driving. Restrictions to various activities (everyday, physical, leisure and social) were reported as well as wide-ranging impact on patients' sleep, energy levels, independence, emotions, family and other relationships. Moderators of the impact of hip fracture on patients were also identified and incorporated into the conceptual model. **CONCLUSIONS:** The conceptual model summarizes important experiences and related impacts of hip fracture from the patient's perspective and demonstrates the wide-ranging effects in other areas of patients' lives during their recovery.

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DETERMINING THE TRUE IMPACT OF DUPUYTREN'S DISEASE: A QUALITATIVE STUDY

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